REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks, which place the application in condition for allowance.

Attached hereto is a marked up version of the changes made to the specification by this amendment. The attachment is captioned **"Version With Markings to Show Changes Made."**

Claims are amended and new claims 40-57 added, with support therefor found throughout the specification.

No new matter is added.

It is submitted that these claims as previously pending and the claims herewith are patentably distinct from the references cited by the Examiner, and that these claims are and were in full compliance with the requirements of 35 U.S.C. §112. The amendment and addition of the claims and the remarks herein are not made for purposes of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments, additional claims and remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

Indeed, it is noted that claims are broadened by this Amendment, such that there can clearly be no estoppel; e.g., "comprising" is inserted into certain claims. Also, some claims use "obtainable" whereas other claims use "obtained". The term "obtainable" is not meant to limit the claimed subject matter to only that which is obtained by any process recitations that follow the term "obtained". That is, the claims using "obtainable" are not product-by-process claims and are not to be construed as such after issuance. Hence, such claims are different from the claims using the term "obtained".

Also, it is noted that the present application, at page 6, cites Hunter et al., U.S. Patents Nos. 5,952,467 and 5,972,697 and Hunter et al. PCT WO 97/17986. With respect to subject matter in the aforementioned Hunter et al. Patents and PCT and any other pending Hunter et al. applications that claim priority from the applications from which those Patents issued or from the PCT or from any applications cited on the face of that PCT, it is respectfully requested that there be a comparison with the Lu, Hanes and Hunter article in Nature 380:544-547 (11, April 1996); and, that if there is any assertion by Hunter et al. that herein inventor Steven Hanes is not an inventor of subject matter in any Hunter et al. application or patent, it is further respectfully

requested that the USPTO insist that Hunter et al. obtain such as statement from herein inventor Steven Hanes because in addition to the aforementioned article, it is also noted there are also notebook records of Dr. Hanes showing work in PCT/US96/17334 (WO 97/17986 and US Patents Nos., 5,952,467 and 5,972,697. This information is called to the attention of the herein Examiner because the Hunter et al., U.S. Patents Nos. 5,952,467 and 5,972,697 and Hunter et al. PCT WO 97/17986 are not believed to be "by another" or "by others" and so that the herein Examiner may duly act on this information if there remains a pending Hunter et al. application.

I. THE REJECTIONS UNDER 35 U.S.C. §112 ARE OVERCOME

Claim 27 is rejected under 35 U.S.C. §112, second paragraph as allegedly being vague and indefinite. The rejection is respectfully traversed. Claim 27 has now been cancelled, rendering this rejection moot. Consequently, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1, 2, 5, 6, 20-26 and 30–39 are rejected under 35 U.S.C. §112, first paragraph as allegedly being non-enabled. Claims 2, 20-22, 25-26, 30, 31, 33, 35 and 37 have been cancelled, rendering the rejection of these claims moot. Consequently, the rejection remains only for claims 1, 5, 6, 23, 24, 32, 34, 36, and 38-39. The rejection is respectfully traversed.

Specifically, the Office Action states, *inter alia*, "that there is no support [for] a nucleic acid molecule which encodes a fragment of a polypeptide (i.e., fragment with 97% homology) and a primer or probe which specifically binds to a nucleic acid molecule comprising a nucleotide sequence encoding [a] variant of CaESS1." The amendments to the claims remove the language '97% homology', such that the Applicant believes the claims should now be allowable.

In addition, the Office Action (at 5) states that the "presently claimed polypeptide having enzymatic activity and an isolated nucleic acid molecule hybridizing thereto specifically to the nucleotide sequence set forth in SEQ. ID. NO: 1 have not been shown to have activity so that the claimed invention is enabled." The Examiner is respectfully invited to review Examples 1-3 in the instant application, wherein the activity of such is clearly demonstrated.

However, it is respectfully suggested that the present application is being treated as a 1st generation application, instead of as the 3rd generation application it is. Briefly, the Patent Office views on patenting genes can be summarized into three generations of applications, based on the amount of disclosure contained in an application:

Generations:

1st generation: Partial sequences, no ORFs.

2nd generation: ORF disclosed w/ putative function only.

3rd generation: Fully characterized nucleic acid *including* expression of any encoded protein and full functional analysis of said protein.

The instant application sets forth the DNA, amino acid sequence and the utility associated with both. Clearly, the present application should be considered a 3rd generation application, and be granted the leniency deserved thereof (i.e., the Applicant should be entitled to language which is broader than "consisting of"). To further the Applicant's position, submitted herewith is a copy of a manuscript (of which the Applicant is an author) submitted to GENETICS on July 25, 2001, and published January 2002, volume 160, pages 37-48 entitled "The Ess1 Prolyl Isomerase is Required for Growth and Morphogenetic Switching in *Candida albicans*."

Also, submitted herewith are selected slides from the West Coast Road Show covering the presentations by Brian Stanton and John Doll. Specifically, please make note of the sections covering enablement requirements, possession of invention and the generations used in examining applications containing amino acid sequences. Indeed, the present application meets all such requirements.

In light of the amendment to the claims and the foregoing arguments, the pending claims are enabled by the specification and therefore, the rejection is obviated.

Consequently, it is respectfully requested that the Section 112 rejections be reconsidered and withdrawn.

II. THE REJECTIONS UNDER 35 U.S.C. §102 ARE OVERCOME

Claims 24 and 39 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Springer et al (U.S. Patent 5,489,513). The rejection is respectfully traversed.

It is again respectfully pointed out that Applicants' invention is directed to, *inter alia*, a gene essential for *Candida albicans* growth, the *CaESS1* gene, and diagnostic and therapeutic compositions and methods involving the gene, protein, or fragments thereof. Springer *et al.* do not teach or suggest either the sequence of *CaESS1* or a primer or probe which specifically hybridizes to it. Rather, Springer *et al.* disclose a "gene probe", 431-19, which may or may not code for a functional gene product, and several 100 base pair oligonucleotide probes that

hybridize with the gene probe. Furthermore, the probe of Spinger *et al.* has not been shown to encode CaEss1 or to specifically hybridize to SEQ ID NO: 1.

It is againrespectfully pointed out that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.,* 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. *See Chester v. Miller,* 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. *See In re Donohue,* 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Springer *et al.* clearly does not contain all of the elements of the claimed invention, since neither the sequence of *CaESS1,* nor a primer or probe which specifically hybridizes to it, are disclosed. And note also the "consisting of" and "consisting essentially of" transitions and how these transitions, as well as functional recitations, distinguish over the art. Therefore, the cited document does not teach or suggest the present invention.

Claims 5, 6, 27, 30 and 31 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Accession number Y 13120 (May 27, 1997) and Accession Number AA 182274 (January 6, 1997). The rejection is respectfully traversed.

Again, this rejection cannot stand. Claims 27, 30 and 31 have been cancelled, rendering the rejection of those claims moot. Claims 5 and 6 for primers that specifically hybridize to SEQ ID NO: 1, or specific sequences. Accession Numbers AA 182274 and Y 13120 do not contain all of the elements of the claimed invention. Further, accession numbers do not contain an enabling disclosure that would enable the skilled artisan to make and use the presently claimed invention. Without an enabling disclosure, a reference may not be properly used as the basis for a §102 rejection. Again, the Examiner is respectfully invited to review the relevant case law cited above.

Therefore, it is respectfully requested that the Section 102 rejections be reconsidered and withdrawn.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, prior to any paper issuing other than a Notice of Allowance, another interview is respectfully requested and the Examiner is further respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for the interview.

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and thanks her for the courtesies extended.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS[3]:

1. (Not Further Amended) An isolated or purified nucleic acid molecule consisting of the nucleotide sequence set forth in Figure 1 (SEQ ID NO: 1).

5. (Twice Amended) A primer [or probe] which specifically hybridizes to the nucleic acid molecule of claim 1.

6. (Amended) The primer [or probe] of claim 5 comprising OW-216 or OW-221 (SEQ ID NOS: 3, 6).

23. (Twice Amended) A method for obtaining an isolated nucleic acid molecule encoding *Candida albicans* Ess1 (CaEss1) comprising performing a polymerase chain reaction on a sample suspected to contain *Candida albicans ESS1* (*CaESS1*) using primers [or probes] which specifically hybridize thereto as claimed in claim 5.

24. (Not Amended) An isolated or purified nucleic acid molecule comprising the nucleotide sequence set forth in Figure 1 (SEQ ID NO: 1), and encoding a polypeptide having the enzymatic activity of *Candida albicans* Ess1 (CaEss1).

28. (Not Amended) An isolated nucleic acid molecule consisting of OW-216 (SEQ ID NO: 3).

29. (Not Amended) An isolated nucleic acid molecule consisting of OW-221 (SEQ ID NO: 6).

32. (Amended) A method for detecting *Candida albicans* in a sample comprising detecting the presence therein of a nucleic acid molecule of claims 1, 24, [25,] 40, 44, 45, 47 or [26] 48.

34. (Amended) A vector comprising the nucleic acid molecule of claim 1, 24, [25,] 40, 44, 45, 47 or [26] 48.

36. (Amended) A method for preparing *Candida albicans* Ess1 (CaEss1) comprising transforming a vector to contain the isolated nucleic acid molecule of claims 1, 24, [25,] 40, 44, 45, 47 or [26] 48 and obtaining expression thereof.

38. (Not Amended) The method of claim 34 wherein the vector is a yeast.

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[3] All claims now pending by this Amendment are set forth for convenient reference by the Examiner and to assist in printing. Where no amendment is desired, such is parenthetically indicated.

39. (Amended) A method for obtaining an isolated nucleic acid molecule encoding CaEss1 as claimed in claims 1, 24, 40, 44, 45, 47 or 48 comprising [consisting] performing a polymerase chain reaction on a sample suspected to contain *Candida albicans ESS1 (CaESS1)* using primers [or probes] which specifically hybridize thereto.

Please add the following claims, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

--40. (New) An isolated *Candida albicans ESS1 (CaESS1)* or nucleic acid molecule encoding a polypeptide having enzymatic activity of *Candida albicans* Ess1 (CaEss1) wherein said *CaESS1* or said nucleic acid molecule specifically hybridizes to an isolated nucleic acid molecule of claim 1.

41. (New) An isolated *Candida albicans ESS1* (*CaESS1*) or nucleic acid molecule encoding a polypeptide having the enzymatic activity of *Candida albicans* Ess1 (CaEss1) wherein said *CaESS1* or said nucleic acid molecule is obtained from the method of claim 23.

42. (New) An isolated *Candida albicans ESS1* (*CaESS1*) or nucleic acid molecule encoding a polypeptide having the enzymatic activity of *Candida albicans* Ess1 (CaEss1) wherein said *CaESS1* or said nucleic acid molecule is obtained from the method of claim 39.

43. (New) An isolated *Candida albicans ESS1* (*CaESS1*) or nucleic acid molecule encoding a polypeptide having the enzymatic activity of *Candida albicans* Ess1 (CaEss1) wherein said *CaESS1* or said nucleic acid molecule is obtainable from a polymerase chain reaction with a primer of claim 5.

44. (New) An isolated *Candida albicans ESS1* (*CaESS1*) or nucleic acid molecule encoding a polypeptide having the enzymatic activity of *Candida albicans* Ess1 (CaEss1) wherein said *CaESS1* or said nucleic acid molecule is obtainable from a polymerase chain reaction with an isolated nucleic acid molecule of claim 28.

45. (New) An isolated *Candida albicans ESS1* (*CaESS1*) or nucleic acid molecule encoding a polypeptide having the enzymatic activity of *Candida albicans* Ess1 (CaEss1) wherein said *CaESS1* or said nucleic acid molecule or an isolated nucleic acid molecule is obtainable from a polymerase chain reaction with an isolated nucleic acid molecule of claim 29.

46. (New) An isolated *Candida albicans ESS1* (*CaESS1*) or nucleic acid molecule encoding a polypeptide having the enzymatic activity of *Candida albicans* Ess1 (CaEss1)

wherein said *CaESS1* or said nucleic acid molecule is obtained from a polymerase chain reaction with a primer of claim 5.

47. (New) An isolated *Candida albicans ESS1* (*CaESS1*) or nucleic acid molecule encoding a polypeptide having the enzymatic activity of *Candida albicans* Ess1 (CaEss1) wherein said *CaESS1* or said nucleic acid molecule is obtained from a polymerase chain reaction with an isolated nucleic acid molecule of claim 28.

48. (New) An isolated *Candida albicans ESS1* (*CaESS1*) or nucleic acid molecule encoding a polypeptide having the enzymatic activity of *Candida albicans* Ess1 (CaEss1) wherein said *CaESS1* or said nucleic acid molecule or an isolated nucleic acid molecule is obtained from a polymerase chain reaction with an isolated nucleic acid molecule of claim 29.

49. (New) A method for detecting *Candida albicans* in a sample comprising detecting the presence therein of a nucleic acid molecule of claim 40.

50. (New) A vector comprising the nucleic acid molecule of claim 40.

51. (New) A method for preparing *Candida albicans* Ess1 (CaEss1) comprising transforming a vector to contain the isolated nucleic acid molecule of claim 40 and obtaining expression thereof.

52. (New) A method for detecting *Candida albicans* in a sample comprising detecting the presence therein of a nucleic acid molecule of claim 43.

53. (New) A vector comprising the nucleic acid molecule of claim 43.

54. (New) A method for preparing *Candida albicans* Ess1 (CaEss1) comprising transforming a vector to contain the isolated nucleic acid molecule of claim 43 and obtaining expression thereof.

55. (New) A method for detecting *Candida albicans* in a sample comprising detecting the presence therein of a nucleic acid molecule of claim 46.

56. (New) A vector comprising the nucleic acid molecule of claim 46.

57. (New) A method for preparing *Candida albicans* Ess1 (CaEss1) comprising transforming a vector to contain the isolated nucleic acid molecule of claim 46 and obtaining expression thereof.